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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

vs.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON,

Defendants.

Case No.: 3:17-cv-07250-JST

MOTION TO DISMISS AMENDED COMPLAINT BY DEFENDANTS JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, AND JOHNSON & JOHNSON

Judge: Hon. Jon S. Tigar
Date: May 16, 2019
Time: 2:00 PM
Place: Courtroom 9, 19th Floor, Phillip Burton Federal Building

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on May 16, 2019 at 2:00 PM, or as soon thereafter as the matter may be heard in the above-entitled Court located at 450 Golden Gate Avenue, San Francisco, California 94102, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson by and through counsel, will and hereby do move this Court to Dismiss the Amended Complaint (Dkt. 7) pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6).

This motion is based on this Notice of Motion and Motion, its Memorandum of Points and Authorities, its Request for Judicial Notice ("RJN") and related exhibits, all other papers and pleadings on file, and argument of counsel at any hearing of this Motion.

ISSUE TO BE DECIDED

1. Does the Amended Complaint fail to state a claim upon which relief may be granted pursuant to the Federal Rules of Civil Procedure 9(b) and 12(b)(6)?

MEMORANDUM OF POINTS AND AUTHORITIES

Relator Zachary Silbersher is a New York City-based patent attorney[1] whose practice comprises prosecuting and challenging patents, including *inter partes* review ("IPR") proceedings.[2] More recently, Relator has taken up a side career as a serial litigant, converting patent claims into False Claims Act ("FCA") suits. To date, Relator has filed at least three near-identical FCA actions premised on alleged inequitable conduct before the U.S. Patent and Trademark Office ("USPTO").[3] In none of these is Relator the typical *qui tam* plaintiff, an employee, a contractor, or other "insider" disclosing inside information of wrongdoing. Quite the opposite. Here, Relator has no relationship with Defendants[4] at all. Instead, as the Amended Complaint, ECF 7 ("Complaint" or "AC"), makes clear, Relator has simply repackaged publicly available information and arguments previously filed in patent proceedings and now presents them as purported fraud. As such, Relator's allegations are barred by the FCA. Moreover, despite his lengthy Complaint, Relator fails to plead adequately the submission of a false claim, materiality, or scienter, all necessary for an FCA claim to survive. For all the reasons set forth herein, the Complaint should be dismissed with prejudice.

BACKGROUND

Defendants are manufacturers of pharmaceutical products who market and sell abiraterone acetate ("abiraterone") under brand name Zytiga. AC ¶ 2.[5] Zytiga is a life-extending prescription drug used to treat metastatic castration-resistant prostate cancer ("mCRPC")—an advanced and deadly form of prostate cancer that is resistant to traditional first-line treatments—that is approved and prescribed for use with prednisone, a glucocorticoid. *See id.* Relator alleges that Defendants have

[1] *See* Kroub, Silbersher & Kolmykov PLLC, http://www.kskiplaw.com/silbersher.html.
[2] An IPR is a statutory procedure by which a third party may request cancellation of a patent claim because it does not meet the standards for patentability. *See* 35 U.S.C. §§ 311–319.
[3] *See U.S. ex rel. Silbersher v. Valeant Pharm. Int'l, Inc.*, No. 18-cv-01496-JD (N.D. Cal. Oct. 23, 2018); *U.S. ex rel. Silbersher v. Allergan PLC*, No. 18-cv-03018-JCS (N.D. Cal. May 5, 2018). In cutting and pasting his complaint in this case, Relator forgot in several paragraphs to change the name of the relevant drugs. *See, e.g.*, AC ¶¶ 9, 114–15. Additional copycat complaints may remain under seal. Lastly, Relator and his lawyers are also litigating identical claims packaged as antitrust suits. *See In re: Restasis*, No. 18-md-02819-NG-LB (E.D.N.Y).
[4] The Amended Complaint names several Defendants and asserts actions taken by some or all of them. For convenience, the term "Defendants" is used herein generically to refer to some or all of the Defendants without parsing which one allegedly took a particular action.
[5] While Defendants accept Relator's well-pled allegations for this motion, if this matter proceeds Defendants will vigorously dispute Relator's false, misleading, and legally insufficient claims.

violated the FCA by submitting or causing to submit false claims for payment for Zytiga to various federal programs since December 2016. *Id.* ¶¶ 112–16.

Relator's theory for FCA liability is an attenuated one. Relator does not claim that Defendants factually misrepresented the amount of Zytiga sold or the reimbursable price. Instead, Relator claims that Defendants corrupted the federally-agreed discounted price itself. Relator's claim starts with the process by which the federal government procures drug discounts. *Id.* ¶ 105. To be listed on the Federal Supply Schedule ("FSS") or to participate in various federal drug programs, a manufacturer must submit specified commercial pricing information to allow government officials to confirm that the manufacturer's offered price is "fair and reasonable" or otherwise accurate. *See id.* ¶¶ 105–06. Relator does not assert that Defendants submitted the wrong, incorrect, or incomplete pricing data, or engaged in any other impropriety during the procurement pricing process. Instead, Relator claims that the market price data Defendants supplied had itself been unlawfully inflated and was therefore *per se* not "fair and reasonable" or otherwise appropriate. *Id.* ¶ 110.

Relator claims Defendants rigged the price for Zytiga by excluding generic competitors from marketing mCRPC treatments using abiraterone and prednisone. *Id.* ¶¶ 4–5. Defendants did so, Relator contends, by means of the FDA's "Orange Book," which lists, *inter alia*, patent information for FDA-approved drugs. *Id.* ¶ 41. Any manufacturer submitting an application to market a generic product (an "ANDA") must indicate whether the proposed drug implicates a patent listed in the Orange Book, and, if so, must certify that the patent is either not infringed or is invalid (a "Paragraph IV certification"). *See* 21 C.F.R. § 314.94(a)(12)(i)(A)(4); AC ¶ 47(d). Under the Hatch-Waxman Act, the lodging of a Paragraph IV certification allows the patent-holder to bring an action for infringement, and the filing of such an action automatically stays the entry of generics into the market pending resolution of the suit, usually for 30 months or until judgment of non-infringement or invalidity is entered in the district court. 21 U.S.C. § 355(c)(3)(C).

Historically, sales of Zytiga have been protected by two patents: U.S. Patent No. 5,604,213 ("the '213 Patent"), *see* RJN, Ex. A, which expired in December 2016, and U.S. Patent No. 8,822,438 ("the '438 Patent"), *see* RJN, Ex. B, granted in 2014 and set to expire in 2027. *See* AC ¶¶ 83–84. Following its issuance by the USPTO, Defendants listed the '438 Patent in the Orange Book. *Id.* ¶ 83.

Shortly thereafter a number of generic manufacturers filed ANDAs containing Paragraph IV certifications contesting the validity of the '438 Patent. *Id.* ¶¶ 85–86. On July 31, 2015, Defendants filed suit for infringement in the District of New Jersey, which triggered the temporary stay on all generic entry. 21 U.S.C. § 355(c)(3)(C). *See also* AC ¶ 50. The statutorily mandated stay, Relator contends, prevented generic competition and artificially inflated the price of Zytiga. *Id.* ¶ 93.

But that is not the end of Relator's theory of falsity. Instead, the Court must rewind even further to a separate proceeding before a different government agency—the USPTO. When initially approved by the FDA in 2011,[6] Zytiga was covered only by the '213 Patent, issued in 1997, which claimed the compound abiraterone acetate. *See* RJN, Ex. A. In 2011, researchers at Cougar Biotechnology ("Cougar")[7] filed application number 13/034,340 ("the '340 Application") to patent a method of administering abiraterone with prednisone to treat prostate cancer. AC ¶ 67. The USPTO initially denied the '340 Application for obviousness. *Id.* ¶¶ 68–69. Upon further consideration, however, the USPTO found that there were secondary considerations—such as the claimed invention's commercial success—and, in 2014, it issued the '438 Patent. *Id.* ¶¶ 25, 78. Relator claims that Defendants engaged in "inequitable conduct" in presenting Zytiga's history of commercial success to the USPTO, thereby fraudulently inducing the USPTO to issue the '438 Patent. *See id.* ¶ 82.

Thus, the sweeping arc of Relator's theory: Defendants defrauded the USPTO into issuing a patent; which Defendants listed in the Orange Book; which required generic manufacturers to file Paragraph IV certifications; which allowed Defendants to file an infringement action; which triggered a stay; which temporarily excluded generics from the market; which allowed Defendants to charge higher prices for Zytiga; which elevated the market prices submitted to GSA; which misled Government officials into agreeing to a price for Zytiga that was too high; which made Zytiga's federal list price not "fair and reasonable"; which made claims for reimbursement at that price false. As explained in detail below, this theory fails for multiple reasons.

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[6] The FDA initially approved Zytiga only for the treatment of "chemo-refractory" patients (*i.e.*, who have previously undergone chemotherapy), AC ¶ 58, before expanding approval in 2012 to "chemo-naïve" patients (*i.e.*, patients who have not previously undergone chemotherapy). *Id.* ¶ 77(d).

[7] Defendants acquired Cougar in 2009, after Cougar had filed an initial application to patent the conjunctive use of abiraterone and prednisone to treat mCRPC. *See id.* ¶ 23. That application was subsequently abandoned. *See* RJN, Ex. B.

Relator was not the first (nor the second, nor even the third) party to challenge the '438 Patent and dispute the commercial success of the claimed invention. In Defendants' infringement action, filed in July 2015, the defendant generic companies contested the validity of the patent. After that suit was filed, starting on December 4, 2015, five generic pharmaceutical companies filed IPR petitions, similarly contending that the invention claimed in the '438 Patent was obvious and had not enjoyed commercial success. Not until December 2017—more than two years later and after completion of dispositive briefing in each of the IPRs—did Relator file this action under seal.

Relator's Complaint borrows liberally from the IPRs, contending that the '438 Patent should never have issued, and also accusing Defendants of misconduct before the USPTO. AC ¶¶ 63–82. In particular, Relator alleges that Defendants misrepresented specific market-share data relating to Zytiga and, in so doing, overstated Zytiga's commercial success by withholding competitor FDA approval dates and using improper metrics of commercial success. *Id.* ¶¶ 75–79. Relator further points to a litany of alleged misstatements and/or omissions in an attempt to poke holes in the commercial success of the claimed invention, *i.e.*, the conjunctive use of abiraterone and prednisone to treat prostate cancer. *Id.* ¶ 80(a)–(e). Relator contends that Defendants acted in bad faith, and that the USPTO awarded the '438 Patent solely because of these misstatements and omissions. *Id.* ¶¶ 75, 78–79.

Within a month of Relator filing this action, the PTAB issued final written decisions deeming the '438 Patent invalid. The District of New Jersey followed suit in October 2018 after a bench trial.[8] *See* ECF 571, Consolidated Opinion, *BTG Int'l, Ltd. v. Amneal Pharm. LLC*, No. 2:15-cv-05909-KM-JBC (D.N.J. Oct. 31, 2018). Throughout the various challenges to the '438 Patent, and to this day, the federal government and individual states continue to make payments and reimbursements for Zytiga. *See*, *e.g.*, AC ¶¶ 121–22 (alleging federal government "continues to pay the claims that the Government would not have paid but for Defendants' illegal conduct"). On September 17, 2018, following its investigation into Relator's claims, the United States declined to intervene in the present action, with the Plaintiff States similarly declining on October 25, 2018. The seal was lifted on

[8] Defendants have appealed the PTAB and District Court rulings to the United States Court of Appeals for the Federal Circuit, where they are consolidated for review. *See BTG Int'l Ltd. v. Amneal Pharma, LLC*, No. 19-1147 (Fed. Cir. docketed Oct. 31, 2018).

October 20, 2018 and Defendants were served. Defendants' motion followed.

LEGAL STANDARD

A complaint must be dismissed if it does not "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[L]abels and conclusions" or "formulaic recitation[s] of the elements of a cause of action" are insufficient, as are "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 545). Because FCA claims are premised on fraud, they must be pled with the particularity demanded by Rule 9(b). *See, e.g., U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011); *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010). In reviewing the sufficiency of the complaint, courts may consider the contents of the complaint and its attached exhibits, documents incorporated into the complaint by reference, and matters properly subject to judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007). While courts freely grant leave to amend, amendment is inappropriate when the complaint's defects cannot be remedied by the allegation of more facts. *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000).

ARGUMENT

I. RELATOR'S CLAIMS ARE PRECLUDED BY THE PUBLIC DISCLOSURE BAR

An FCA claim may not be based on previously disclosed allegations or transactions, unless the relator qualifies as an "original source" of the information. *See* 31 U.S.C. § 3730; *U.S. ex rel. Found. Aiding The Elderly v. Horizon W. Inc.*, 265 F.3d 1011, 1013 (9th Cir. 2001). This bar encourages whistleblowers with independent and valuable insider information to come forward, "while discouraging litigation by plaintiffs who have no significant information of their own to contribute." *U.S. ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 570 (9th Cir. 2016). Relator's claims here are based on previously disclosed information for which he is not an original source. The Court can—and should—dismiss the Complaint on this basis alone.

A. Relator's Essential Allegations Were Previously Disclosed.

The Complaint relies entirely on publicly available information. Drawn from patent filings, court pleadings, IPR petitions, and other media searches, Relator merely repackages previously

published material for Relator's pecuniary gain. Relator's lawsuit is the paradigmatic "parasitic lawsuit[]" Congress sought to preclude. *Mateski*, 816 F.3d at 577 (quoting *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 413 (2011)).

The public disclosure bar applies when "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" previously "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. § 3730(e)(4)(A). As the Ninth Circuit has explained, "allegations" includes "direct claims of fraud" while "transactions" includes "facts from which fraud can be inferred." *Amphastar Pharm. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 703 (9th Cir. 2017) (quoting *Mateski*, 816 F.3d at 571). To discern whether the bar applies, courts use the "X + Y = Z" formula, where "Z represents the allegation of fraud and X and Y represent its essential elements," *i.e.*, the misrepresented facts and the true state of affairs. *Id.* Not every allegation or transaction listed in a complaint must have been publicly disclosed for the public disclosure bar to apply, so long as a "critical mass" is publicly available. *Amphastar*, 856 F.3d at 703.

The Complaint rests at bottom on the contention that Defendants defrauded the USPTO into agreeing that the '438 invention (*i.e.*, the co-administration of abiraterone acetate with prednisone) had enjoyed commercial success by: (1) misrepresenting Zytiga's commercial success and/or (2) by failing to disclose information showing that its commercial success was not attributable to the claimed invention. Here, nearly all—and certainly a "critical mass"—of Relator's allegations had been disclosed previously through IPR petitions alleging that Defendants misrepresented the scale and source of Zytiga's commercial success as well as through a host of online media sources reporting the facts Relator claims Defendants should have disclosed to the USPTO. *See U.S. ex rel. Hong v. Newport Sensors, Inc.*, SACV 13-1164-JLS, 2016 WL 8929246, at *5 (C.D. Cal. May 19, 2016) ("Information publicly available on the Internet generally qualifies as 'news media.'") (collecting cases); *see also U.S. ex rel. Unite Here v. Cintas Corp.*, No. C 06-2413, 2007 WL 4557788, at *14 (N.D. Cal. Dec. 21, 2007) (same). Thus, Relator's claims fall within the "generally broad scope" of the public disclosure bar. *Schindler*, 563 U.S. at 408.

1. Relator's Allegations Were Disclosed in Publicly Available IPR Petitions.

The five IPR petitions challenging the '438 Patent were all lodged well before Relator filed the instant action and all are publicly available on the Patent Trial & Appeal Board's ("PTAB") website.[9] At least two (Amerigen and Wockhardt) were reported in news articles disclosing their docket numbers.[10] *See U.S. ex rel. Proctor v. Safeway, Inc.*, No. 11-cv-3406, 2016 WL 7017231, at *12 (C.D. Ill. Dec. 1, 2016) (article identifying lawsuit constitutes a public disclosure). Three (Amerigen, Wockhardt, and Mylan) were all disclosed in Johnson & Johnson's ("J&J") SEC reports.[11] *See U.S. ex rel. Calilung v. Ormat Indus., Ltd.*, No. 3:14-CV-00325-RCJ, 2015 WL 1321029, at *16 (D. Nev. Mar. 24, 2014) (SEC filings constitute public disclosure); *U.S. ex rel. Ryan v. Endo Pharm., Inc.*, 27 F. Supp. 3d 615, 628 n.16 (E.D. Pa. 2014) (same).

Relator's claims are "substantially similar" to allegations raised in the IPR proceedings. *U.S. ex rel. Solis v. Millennium Pharm., Inc.*, 885 F.3d 623, 626 (9th Cir. 2018). Indeed, Relator *cites to* those IPR proceedings, demonstrating his reliance on them. *See* AC ¶ 92.

The IPR petitions asserted Relator's core complaint: that J&J failed to demonstrate a nexus between Zytiga's commercial success and the claimed invention. *Compare* RJN, Ex. D at 48–52 (arguing that J&J "presented *no* evidence to suggest that the claimed invention, rather than the prior art abiraterone acetate, was responsible for any commercial success of Zytiga.®"); RJN, Ex. E at 51–54 (arguing that "any commercial success of Zytiga® has not been shown to derive from the claimed invention, *i.e.*, the combination of abiraterone acetate and prednisone"); RJN, Ex. F at 60–62 (arguing that Defendants "failed to provide any evidence [of a] nexus between the Zytiga® sales and the '438 patent"), *with* AC ¶¶ 80(b)–(g), (i) (alleging facts, not disclosed to the PTO, that purportedly demonstrate Zytiga's commercial success lacked required nexus to the claimed invention but was attributable to other factors).

[9] Amerigen Pharm., Ltd., Argentum Pharm. LLC, Mylan Pharm. Inc., Wockhardt Bio AG, and Actavis Laboratories Fl, Inc. filed IPR petitions between December 2015 and February 2017—long predating Relator's FCA filing in December 2017. *See* RJN, Ex. D (Amerigen); RJN, Ex. E (Mylan); RJN, Ex. F (Wockhardt).

[10] *See* RJN, Ex. P at 1 (discussing the Amerigen petition); RJN, Ex. Q at 1–2 (discussing the Wockhardt petition).

[11] *See* RJN, Ex. K (Nov. 4, 2016 10-Q); RJN, Ex. L (Aug. 4, 2016 10-Q); RJN, Ex. M (May 9, 2016 10-Q); RJN, Ex. N (Feb. 24, 2016 10-K).

Relator merely repurposes the petitions' arguments that Zytiga's commercial success is owed to the "effectiveness of abiraterone acetate in treating prostate cancer," RJN, Ex. D at 51; *see also* RJN, Ex. E at 53 (same); RJN, Ex. F at 60–62 (arguing commercial success cannot be based on characteristics of claimed method already known in the prior art), when he alleges: (i) the drug resistant nature of mCRPC limits the long-term efficacy of any one drug, therefore any new anti-cancer drug is likely to have some commercial success, AC ¶ 80(b); (ii) "Zytiga was recommended in some cases because it was the least toxic" of available drugs, not because of any feature of the claimed invention, *id.* ¶ 80(d); and (iii) the alleviation of certain side effects, which Relator alleges was the innovation claimed by the '438 Patent, "may not have actually been a factor in the decision to prescribe or take Zytiga," *id.* ¶ 80(f).

Relator's contentions that Defendants misrepresented the market for drugs to treat mCRPC and the commercial success of Zytiga's competitors, *id.* ¶ 77, are similarly lifted from the IPR petitions. For instance, Wockhardt alleged that J&J's statement that Zytiga continued to experience commercial success even after the introduction of competitor Xtandi were misleading in light of Xtandi's subsequent takeover of Zytiga's market share; Relator cites to that same Zytiga-to-Xtandi market shift. *Compare* RJN, Ex. F at 62–63 (loss of market share against Xtandi "is particularly notable in light of the applicants' argument during prosecution that Zytiga®'s continued commercial success after the introduction of Xtandi® was further evidence of the commercial success of the invention"), *with* AC ¶ 77(a) (alleging that Xtandi overtook Zytiga in market share in the relevant market). That Xtandi exceeded Zytiga in sales was also reported in the media. *See, e.g.*, RJN, Ex. R at 2 of 4 (business article).

Relator also repeats the IPR petitions' attack on Defendants' definition of the relevant market for measuring commercial success, going so far as to cite to the very same slide within a business document submitted by J&J to the USPTO. Relator attacks the slide's market-share comparison as fraudulent because it compared Zytiga and Xtandi sales in a submarket for which Xtandi had not yet received FDA approval. AC ¶ 77(d); RJN, Ex. C at slide 12 (June 4 submission). The IPR petitions similarly challenged the data as "deficient" and contended that Zytiga's commercial success was in fact less robust. *See* RJN, Ex. D at 49–50; RJN, Ex. E at 52–53.

Finally, Relator repeats the IPR petitions' argument that the '213 Patent "blocked" the commercial development of abiraterone, which "casts substantial doubt" on Zytiga's sales success. *Compare* AC ¶ 80(e), *with* RJN, Ex. D at 57–58, 59 ("The ability of the patentees of the '213 to block additional research and development of abiraterone acetate limits the relevance of commercial success for the '438 patent."); RJN, Ex. E at 59–61 ("'213 patent was a blocking patent that limited economic incentives to develop the invention of the '438 patent."); RJN, Ex. F at 56–59 (discussing Janssen's "blocking exclusivity" of the '213 Patent). Relator also repeats the canard that this "blocking patent" was not disclosed to the USPTO. *Compare* AC ¶ 80(e), *with* RJN, Ex. D at 34; RJN, Ex. E at 35. The '213 Patent was disclosed publicly and to the USPTO through the '340 Application's specification. *See* RJN, Ex. I at 7, 10 ('340 Application specification). And the expected impact of the '438 Patent following expiration of the '213 Patent was covered by industry news.[12] Because a critical mass of the transactions underlying Relator's allegations were publicly disclosed, the Court need not go further to find that the public disclosure bar applies.

2. The Transactions Underlying Relator's Allegations Were Publicly Disclosed Through A Variety of Sources.

A critical mass (*i.e.*, the "X" and the "Y") was also publicly disclosed in the patent prosecution itself and in widely available internet reporting. Relator alleges that Defendants made misleading statements or omissions (*i.e.*, the "X") in their June 4, 2013 submission to the USPTO (the "June 4 submission"), AC ¶¶ 75–77, 80, all of which were submitted to the government as part of a federal hearing in J&J's patent prosecution. *See A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1244 (9th Cir. 2000) ("'Hearing' in this context is synonymous with 'proceeding,' and, for purposes of raising the public disclosure bar, encompasses publicly-filed documents, 'even if they are not the subject of a hearing.'") (citations omitted). The June 4 submission is publicly available on the USPTO's website through Public PAIR ("Patent Application Information Retrieval"), a federally maintained database that compiles prosecution histories and reports of patents and patent applications. *See Hong*, 2016 WL 8929246, at *5; *see also Schindler Elevator Corp.*, 563 U.S. at 407–08 (adopting

[12] *See, e.g.*, RJN, Ex. S at S492–93 (discussing how the '438 Patent will "extend the period of exclusivity" beyond the '213 Patent).

the ordinary meaning of "report," for purposes of the public disclosure bar, as "something that gives information" or a "notification" or "[a]n official or formal statement of facts or proceedings") (quoting *Black's Law Dictionary* 1300 (6th ed. 1990)).

Much of the information Relator claims *should* have been disclosed to the USPTO (*i.e.*, the "Y"), was publicly disclosed through that same June 4 submission or other media sources.

With respect to Zytiga's market share, Relator alleges that Defendants misled the USPTO by: (1) comparing Zytiga's market share in the chemo-naïve market to that of Xtandi, when Xtandi had yet to be FDA-approved for that submarket, AC ¶¶ 77(a)–(d); (2) withholding the dates of Xtandi's FDA approvals, *id.* ¶ 77(d); and (3) providing evidence of market share based on patient-share data rather than direct sales, "because patients suffering from prostate cancer often take many drugs," *id.* ¶ 77(e). But all of these facts were publicly disclosed on PAIR through the June 4 submission. For instance, the submission included an FDA press release that announced Xtandi's FDA approval date for the *chemo-refractory* market, and the slide in question separated out the two submarkets in which the products were being compared.[13] Xtandi's initial FDA approval for chemo-refractory patients and the later September 2014 approval for chemo-naïve patients were both also covered by the press.[14] Similarly, J&J's June 4 submission expressly disclosed that the market share was based on patient-data, RJN, Ex. C at slide 12, and also that there is a critical need for second-line therapies for mCRPC patients (*i.e.*, mCRPC patients need and take multiple drugs), *id.* at PDF pgs. 41–46 of 64 (FDA press releases discussing need for and approval of second-line or alternative drug therapies). The latter point has also been covered by scientific and medical articles and was disclosed in the '340 Application specification available on PAIR.[15]

Relator further contends that Defendants should have disclosed that: (1) drug-resistant mCRPC patients must frequently switch medications, which "*suggests* that any new CRPC drug is likely to have some immediate commercial success," AC ¶ 80(b) (emphasis added), and (2) mCRPC drugs

[13] J&J could hardly be expected to disclose the date of Xtandi's FDA approval for the chemo-naïve market, as it had not yet occurred.

[14] *See, e.g.*, RJN, Ex. T at 1 (journal article) (announcing FDA approval for chemo-naïve market); RJN, Ex. U at 1 (journal article) (announcing FDA for chemo-refractory market).

[15] *See, e.g.*, RJN, Ex. V at 170–71 (journal article) (mCRPC patients often need multiple lines of treatment "due to inherent or acquired resistance" of the disease); RJN, Ex. I at 1–2 (discussing need for multiple treatments and that hormone therapies can be used in addition to local therapies).

"extend a patient's life by a few months," which Relator infers to mean that the alleviation of prednisone on abiraterone's side effects "may not" factor in the decision to take a drug, *id.* ¶ 80(f). These disclosures, Relator contends, would have shown the USPTO that Zytiga's success was attributable to its anti-cancer properties, rather than the claimed invention. Whatever their alleged import, these facts *were* disclosed in the June 4 submission[16] and are also widely known among the medical community, as discussed in various scientific articles.[17] *See U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, No. 3:04CV1556, 2011 WL 3875987 (M.D. Pa. Sept. 1, 2011) ("'information in scholarly or scientific periodicals' qualifies as 'news media'") (quoting *U.S. ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002)).

Relator alleges Defendants should have disclosed that Zytiga enjoyed a competitive advantage unrelated to the claimed invention, including that: (1) Zytiga "does not sequence well" with Xtandi and therefore had a natural edge over Xtandi because it launched first, AC ¶ 80(c); and (2) Zytiga has lower toxicity, was cheaper, and offers a more convenient method of administration than its competitors, AC ¶¶ 80(d), (g)–(h). Again, these were all publicly disclosed. The sequencing relationship between Zytiga and Xtandi had been publicly discussed in medical publications.[18] Moreover, abiraterone's "relatively low toxicity profile" was disclosed in a scientific article that was also submitted in the '340 Application,[19] the American Urology Association's 2013 guidelines[20] (which appears to be *expressly cited* in the Complaint[21]), and is readily inferred from the unremarkable observation that Zytiga is not a chemotherapy, but is a hormone-based therapy that is known to be less

[16] J&J provided the USPTO with information concerning the drug-resistant nature of the disease and the value of second-line therapies. RJN, Ex. C at PDF pgs. 41–46 of 64. The FDA press releases in the June 4 submission also provide the "median overall survival rate" for mCRPC drugs. *Id.*

[17] The drug resistant nature of prostate cancer is well documented. *See, e.g.*, RJN, Ex. W at 1–2 (scientific article) (discussing prostate cancer's "resistance to anti-androgen therapies"); RJN, Ex. X (scientific article) (same). Zytiga's effect in prolonging survival is also well disclosed in the media. *See, e.g.*, RJN, Ex. Y at 2 (N.Y. Times article).

[18] *See, e.g.*, RJN, Ex. Z (scientific article) (noting abiraterone (Zytiga)-to-enzalutamide (Xtandi) sequence "might have more favorable efficacy" than an enzalutamide-to-abiraterone sequence); RJN, Ex. X at 1 (discussing cross-resistance of abiraterone and enzalutamide).

[19] RJN, Ex. O at 46. The '438 Patent also expressly lists this article as disclosed during its prosecution. *See* RJN, Ex. B at 2.

[20] RJN, Ex. G at 434, 435 (American Urology Association 2013 Guidelines).

[21] AC ¶ 80(d).

toxic.[22] Moreover, the 2013 price points for Zytiga, Xtandi, and Jevtana were publicly available in the media[23] and each of the drug's method of administration was available on the drug's information website.[24] The preference for an oral medication over an intravenous therapy is not unexpected.[25]

3. The Allegations And Transactions Described In Relator's Complaint Are "Substantially the Same" As The Publicly Disclosed Information.

Taken separately or together, there is no doubt that the allegations and transactions in Relator's Complaint are "substantially the same" as publicly disclosed information. *See Malhotra v. Steinberg*, 770 F.3d 853, 858 (9th Cir. 2014) ("based on" means "substantially similar to"). Relator nowhere identifies non-public, privately held information. No surprise then, that the facts comprising the alleged fraud are virtually indistinguishable from publicly available information. *See U.S. ex rel. Yagman v. Mitchell*, 711 F. App'x 422, 423–24 (9th Cir. 2018) (allegations should be sufficiently specific to distinguish them from publicly available information). Relator's labor in compiling these facts and molding them into his fraud narrative does not render them any less publicly disclosed. *See A-1 Ambulance Serv.*, 202 F.3d at 1245. Nor does Relator's claim that the government purchased drugs at too high a price make these facts any less publicly disclosed. *Amphastar*, 856 F.3d at 704.

B. Relator Is Not An Original Source.

A *qui tam* relator may avoid the public disclosure bar only by qualifying as an "original source," *i.e.*, someone who (1) "prior to a public disclosure … voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing" the *qui tam* lawsuit. 31

[22] *See* RJN, Ex. AA at 1 (scientific article) (noting doctors typically use hormone therapy as a first treatment "because hormone therapy is less toxic and has fewer side effects than chemotherapy").
[23] *See* RJN, Ex. BB at 3 (news article) ("Zytiga costs $5,500 a month, while Xtandi gets $7,450 a month."); RJN, Ex. CC at 2 (N.Y. Times article) (noting Jevtana "costs about $8,000 every three weeks.").
[24] A review of the brand name drugs' webpages, as those sites existed approximately two months before Relator filed his first complaint in December 2017 confirms that the methods of administration for Zytiga and its competitors were fully disclosed. *See* RJN, Ex. DD (Zytiga's website as of Oct. 15, 2017) (Zytiga is an "oral, once-daily" "prescription medication that is used along with prednisone"); RJN, Ex. EE (Xtandi's website as of Oct. 6, 2017) ("Swallow Xtandi capsules whole."); RJN, Ex. FF (Jevtana's website as of Oct. 5, 2017) ("Jevtana is an infusion medicine").
[25] *See, e.g.*, RJN, Ex. R at 3 ("Oral formulations can be favourable over injections and infusions that require healthcare facility visits.").

U.S.C. § 3730(e)(4)(B). Relator has not pled any facts demonstrating that his purported disclosures to the government pre-dated the foregoing public disclosures. AC ¶¶ 17–18. Nor does he plead any facts to support his claim to be an original source beyond his own naked say-so. *Id.* This is plainly deficient, and there is little, if any at all, likelihood that Relator can overcome this defect given that he is an outsider with no connection at all to Defendants.

II. RELATOR HAS FAILED TO PLEAD AN ACTIONABLE FALSE CLAIM

To state a claim for relief under the FCA, Relator must allege "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *U.S. ex rel. Rose v. Stephens Inst.*, 901 F.3d 1124, 1129 (9th Cir. 2018) (citation omitted). A Relator must "'state with particularity the circumstances constituting fraud or mistake,' including 'the who, what, when, where, and how of the misconduct charged.'" *Ebeid*, 616 F.3d at 998 (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)).

"[A]n actual false claim is 'the *sine qua non* of a False Claims Act violation.'" *United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) (quoting *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). That is, the FCA "attaches liability, *not* to underlying fraudulent activity, but to the *claim for payment*." *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (emphases added). In this case, Relator has failed to plausibly plead this foundational element—let alone with particularity.

First, Relator cannot specifically identify the submission of any claim. Second, Relator cannot meaningfully connect any false statement to those unspecified claims. Rather, Relator leans heavily on a laundry list of purportedly misleading statements or omissions, disconnected in time and space from any claim for payment, and attempts to link those events to the claims process through a series of shaky inferences. Even if Relator could establish a proper nexus to payment—and he cannot—his theory of falsity hinges entirely on a claim of "inequitable conduct" before the USPTO that itself is not properly pled. Third and fourth, Relator also fails to plead properly the FCA's demanding standards for materiality and scienter. For all these reasons, Relator's flaws are pervasive and unlikely to be remediated by further pleading. The Complaint should be dismissed with prejudice.

A. Relator Has Not Pled the Submission of a Claim.

From the outset, Relator fails to plead with any degree of specificity that J&J submitted, or caused to be submitted, "an actual false claim." *Kitsap*, 314 F.3d at 1002. He defines the "False Claim[s]" as "(a) claims for Medicare and Medicaid reimbursement for Zytiga prescriptions; and (b) claims for payment relating to government purchases of Zytiga under certain government healthcare programs, such as the Veterans' Administration." AC ¶ 7. Relator liberally sprinkles the term "False Claim" throughout his Complaint but nowhere describes "the who, what, when, where, and how" of the claims at issue. *Ebeid*, 616 F.3d at 998 (internal quotation and citation omitted). For example, while Relator alleges that "Defendants, their employees and agents, individually and in concert, knowingly submitted or caused to be submitted False Claims to the United States Government and the Plaintiff States to secure payments for illegally-inflated price for abiraterone acetate," AC ¶ 102, the Complaint fails to allege the "particular details of a scheme to submit false claims." *Ebeid*, 616 F.3d at 998–99 (quoting *U.S. ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

Recognizing this flaw, Relator concedes he "cannot at this time identify all of the false claims for payment," as he lacks any relationship with J&J or any other potentially relevant entity, including having no access to any relevant records. AC ¶ 120. But Relator's concession that he lacks insider knowledge does not somehow cure the defect. In fact, the Ninth Circuit has rebuffed relators who seek "[t]o jettison the particularity requirements simply because it would facilitate a claim by an outsider." *Ebeid*, 616 F.3d at 999.

Nor do allegations predicated "upon information and belief" satisfy Rule 9(b). Such allegations must still be supported by facts, *see Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1042 (9th Cir. 2010), which Relator lacks. For instance, Relator estimates the number of claims allegedly submitted to the federal government, but that number is wholly unsupported. Relator assumes, without factual basis, that "the number of prescriptions written for Zytiga in 2017 is higher than it was in 2015, even though prices have gone up," making the estimated number of allegedly false claims anything but a "reasonable" inference. AC ¶ 12. Relator states that, "[a]ccording to CMS, various Plaintiff States reimbursed 3,697 Zytiga prescriptions … from January 1 through April 30,

2017," *id.* ¶ 13, leaving the reader to guess at whether some or all of the States reimbursed claims and the alleged "scheme" under which those claims were submitted. And, Relator fails to allege any specific information about the claims themselves, including who submitted the claims, where those unnamed submissions occurred, how they were submitted, or the contents of those submissions.

The remainder of the complaint fares no better. After describing purported false statements *to the USPTO*—which are not false claims for payment and are not actionable under the FCA—Relator generally (and repeatedly) reference "claims" or "False Claims" based on Zytiga sales or reimbursements, but never provides any further detail regarding the actual claims at issue. *E.g.*, AC ¶¶ 97–98, 100–02, 115–16. The dearth of detail concerning the "claims" leaves Relator's Complaint without facts to reliably connect the allegations of fraud to actual claims submitted for payment.

B. Relator Has Not Pled A "False" Claim.

Even if Relator could plead the submission of some claim, he has failed to plead a "false" one. A claim may be false factually or legally. A factually false claim misrepresents the services or goods actually provided, *see U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 900 (9th Cir. 2017), whereas a legally false claim falsely certifies compliance with relevant law, rules, or regulations, either expressly or impliedly, *see Rose*, 909 F.3d at 1017. Relator variously alleges that J&J made false "express representations and implied certifications," AC ¶ 9, "expressly false statements," *id.* ¶ 106, "express and implied misrepresentations," *id.* ¶ 110, and "false certifications of compliance with law," *id.* ¶ 116. This leaves the Court to guess at Relator's actual theory, but Relator fails to state a claim under any of them.

Relator's case relies at bottom on the assertion that Defendants expressly and impliedly represented that Zytiga prices submitted to federal officials, and the data supporting them, were "fair and reasonable" or otherwise accurate when that was not true. *Id.* ¶¶ 9, 10, 104–10. Relator describes the process by which federal officials establish discounts for various drug programs. For the FSS, Relator notes, J&J was required to submit various drug price data and a written justification to confirm that its prices were "fair and reasonable." *Id.* ¶¶ 105–06. Moreover, Relator continues, Defendants were required to submit "truthful information" in order to participate in Medicaid, Medicare Part B, and the Section 340B Drug Pricing Program. *Id.* ¶¶ 108–09. Because Defendants had improperly

inflated the price of Zytiga, Relator asserts, all of Defendants' prices and data were necessarily unfair, unreasonable, and inaccurate. *Id.* ¶¶ 106, 110. No matter how sliced and diced, however, Relator's theory cannot support an FCA claim.

1. Relator Fails to Plead a False Statement Connected to a Claim for Reimbursement.

As an initial matter, Relator fails to identify any false statement made in connection with a claim for reimbursement. To be sure, Relator alleges reams of false statements made at other times and in other places. Yet none of *those* statements support FCA liability. Relators cannot evade the FCA's requirements by identifying "a general sort of fraudulent conduct" without specifying the "particular circumstances of any discrete fraudulent statement." *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1057 (9th Cir. 2011). There is a difference between mere allegations of regulatory violations and a false claim. *Campie*, 862 F.3d at 904. A relator must plead details that connect its fraud allegations to an "overtly false representation in the claim for payment." *U.S. ex rel. Mateski v. Raytheon Co.*, No. 2:06-cv-03614-ODW(KSx), 2017 WL 3326452, at *5 (C.D. Cal. Aug. 3, 2017), *aff'd* 745 F. App'x 49 (9th Cir. 2018). In failing to allege a meaningful nexus between statements allegedly made to (or omitted from) the USPTO, representations made to the GSA, and claims for reimbursement, Relator fails to meet the FCA's most basic requirement—a false claim. *See U.S. ex rel. Promega Corp. v. Hoffman-La Roche Inc.*, No. 03-1447-A (E.D. Va. Sept. 24, 2004) ("misrepresentations to the USPTO" years prior were "disconnect[ed]" from "invoices submitted to the government" and failed to state an FCA claim) (attached hereto as Appendix A).

As to those claims for reimbursement, Relator has not properly pled an *expressly false claim*, either factually or legally. Relator nowhere alleges a factually false claim. Instead, Relator alleges in summary fashion that J&J "submitted or caused submission of False Claims with false certifications of compliance with law." AC ¶ 116. But Relator fails to identify the specific certification or other legal requirement that was violated, and nowhere describes the contents, nature, location, or form of Defendants' purported certification made in connection with a claim for reimbursement. *See Rose*, 909 F.3d at 1017 (express false certification occurs when "entity seeking payment [falsely] certifies compliance with a law, rule or regulation as part of the process through which the claim for payment

is submitted") (quoting *Ebeid*, 616 F.3d at 998)). Any charge of an expressly false claim thus falls far short of the requirements of Rule 9(b).

Nor has Relator alleged a cognizable *impliedly legally false claim*. *See* AC ¶ 9 ("[E]ach False Claim was for an unlawfully elevated, maintained, or stabilized price contrary to express representations and *implied certifications* by Defendants to the federal government that the price of Apriso [sic] reflected in each False Claim was 'fair and reasonable,'… .') (emphasis added)). When "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016). To plead such a claim, a relator must allege two conditions: "first, [that] the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001; *see also Rose*, 909 F.3d at 1018.

Relator does not meet this burden. The lack of detail concerning the claims themselves necessarily precludes the Complaint from showing that J&J (1) made or caused to be made any specific representations concerning Zytiga, which (2) were misleading half-truths due to some statutory, regulatory, or contractual non-compliance. Instead, Relator relies exclusively on representations made to the GSA and other agencies in connection with drug pricing, which in turn rely on purported misstatements to the USPTO. But Relator nowhere connects these supposed misrepresentations and/or omissions to any specific representations made in connection with any claim for payment. *See Escobar*, 136 S. Ct. at 2000; *U.S. ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017) (FCA claim failed "as a matter of law" when relator offered no evidence that alleged false claim "made any specific representations").

Relator's failure in this regard is fatal. "A global indictment of [Defendant's] business is not enough" to draw a link between generic allegations of regulatory fraud and claims for government payment, and it is those claims that are the heart of FCA liability. *Ebeid*, 616 F.3d at 1000. Because Relator has not alleged that Defendants' claims represented compliance with any law or contained any

false statements, his implied false certification FCA claim fails. *Kelly*, 846 F.3d at 325.

2. Relator Fails to Plead a False Statement in Connection with Federal Drug Pricing.

Rather than identify false statements made in connection with a claim for reimbursement, as required, Relator instead relies on representations made to federal officials in connection with drug pricing. Here, Relator asserts that the prices and data Defendants submitted were false, unfair, or unreasonable. Relator's theory, however, rips the phrase "fair and reasonable" from its regulatory moorings, and misrepresents the drug contracting process. Once again, Relator fails to identify a false statement made in this context.

First, the "fair and reasonable" assessment on which Relator relies is not a freewheeling inquiry into the subjective fairness of a drug's price or manufacturer's conduct generally, but rather refers to a specific comparison between specific drug prices. As the GSA document ("the Solicitation") cited by the Complaint explains, AC ¶ 107, the GSA's structured review process is designed in part "to ensure … the Government is receiving a fair and reasonable price." RJN, Ex. H at CP-11. *See also* 48 C.F.R. § 8.404(d) (prices listed on the FSS have been determined to be "fair and reasonable"). Federal "Contracting Officers determine whether prices are fair and reasonable by comparing the prices/discounts that a company offers the government with the prices/discounts offered to commercial customers." RJN, Ex. H at CP-8. As Relator pleads, manufacturers provide the GSA with commercial pricing information and identify a commercial "tracking customer" to allow the GSA to ensure that the prices offered to the government are "fair and reasonable" as compared with the commercial market. AC ¶ 105; RJN, Ex. H at 53. Whether a price is "fair and reasonable" refers only to the comparison between government and commercial prices.[26] RJN, Ex. H at CP-8. In fact, aside from specific required information, such as the offered product's price, most-favored customer information, and tracking customer information, the contracting officer may only "require additional supporting information" about a manufacturer's proposed price "to the extent necessary to determine whether the

[26] A manufacturer separately certifies "that it has on file," as required, an FDA-approved new drug application ("NDA") or abbreviated new drug application ("ANDA") "as appropriate for the items offered in response to the solicitation." RJN, Ex. H at 2. The Solicitation makes no further provision for submitting the approval or requiring the contracting officer to verify the NDA or ANDA.

price(s) offered is fair and reasonable." *Id.* at 53. Manufacturers must present accurate information, but the contracting officer decides whether the offered government price is "fair and reasonable."

Relator nowhere pleads that Defendants submitted incorrect commercial pricing data to the GSA, misidentified the tracking customer, or made any other incorrect representation to GSA or any other federal healthcare agency. Nor does Relator plead that the Zytiga discounts to which the Government agreed were not fair and reasonable in comparison with that accurate commercial pricing data supplied. Instead, Relator asserts that "[b]y definition, Zytiga's pricing that Defendants supplied in connection with the FAA was *not* fair and reasonable, and Defendants' statements to the GSA were expressly false statements." AC ¶ 106; *see also id.* ¶ 110. Relator bases this *ipse dixit* on his allegations concerning purported inequitable conduct before the USPTO. But Relator cites no authority—nor is there any—holding that a drug's patent prosecution history, and the USPTO's reasons for issuing a patent, are relevant in any way to the GSA's determination that a price is "fair and reasonable." It is simply not part of the equation.

Even had Defendants failed to comply with some aspect of the drug price negotiation process, such a regulatory violation still would not support an FCA claim. The procurement process concerns pricing for purposes of program participation—specifically, establishing the price at which a manufacturer *may* offer drugs for sale to the government. "Conditions of participation" in a program, as distinct from "conditions of payment," do not support FCA liability because the former are not integral components of the claim for payment. *See United States v. N. Am. Health Care, Inc.*, No. 14-cv-02401-WHO, 2015 WL 6871781, at *4–5 (N.D. Cal. Nov. 9, 2015). Relator cites no rule making "fair and reasonable" pricing or conduct before the USPTO a component of the claim.

Moreover, regulations such as these "do not *require* 'perfect compliance' to participate." *Id.* at *5. Relator himself notes that providing inaccurate pricing data will require the vendor to "resubmit/correct and redistribute" the correct pricing, "may constitute sufficient cause" for the GSA to cancel a contract, and may call for other remedies including "monetary recovery." AC ¶ 107. The GSA's broad regulatory discretion in this eventuality undermines any argument that strict regulatory compliance is a condition of payment that supports FCA liability. *See N. Am. Health Care*, 2015 WL 6871781, at *5. Indeed,

> To allow FCA suits to proceed where government payment of Medicare claims is not conditioned on perfect regulatory compliance—and where [an agency] may choose to waive administrative remedies, or impose a less drastic sanction than full denial of payment—would improperly permit qui tam plaintiffs to supplant the regulatory discretion granted to [the agency] under the [applicable laws], essentially turning a discretionary denial of payment remedy into a mandatory penalty for failure to meet Medicare requirements.

U.S. ex rel. Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002).

In the final analysis, Relator's theory of falsity is shockingly broad. The FCA "focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme." *Kitsap Physicians Serv.*, 314 F.3d at 1002. Yet, were the Court to accept Relator's construction of the GSA's "fair and reasonable" requirement, it could fairly swallow *any* requirement that could theoretically impact product pricing no matter how attenuated from the claim process. In the patent context alone, this could trigger FCA liability any time a patent is called into question through a patent action or an IPR, and, in all likelihood, on a much more frequent basis separate and apart from those proceedings. Relator's theory would unleash the FCA as an "all-purpose antifraud statute" despite the Supreme Court's explicit instructions to the contrary. *Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine*, 553 U.S. at 672).

3. Relator Fails to Plead Inequitable Conduct Before the USPTO.

Even if factually correct drug pricing data could be deemed false on account of some prior misconduct that elevated the market price (it cannot), and even if such falsity could support an FCA claim (it does not), Relator's claims nonetheless fail because he has failed to plead that Defendants engaged in any such misconduct before the USPTO. In order to sustain his many assertions of breach of the duty of candor to the USPTO, *see* AC ¶¶ 64, 75, 77, 80(a)–(i), Relator must plead that Defendants engaged in inequitable conduct. *See Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 974 n.1 (Fed. Cir. 2010); *MONKEYmedia, Inc. v. Twentieth Century Fox Home Entm't., LLC*, 242 F. Supp. 3d 551, 554 (W.D. Tex. 2017). Relator has failed to do so.

To sustain a claim of fraud on the USPTO, Relator must demonstrate that "the patentee acted with the specific intent to deceive." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288–90 (Fed. Cir. 2011) (en banc). Specific intent, in turn, requires facts sufficient to show that "the

applicant knew of the [information being withheld], knew that it was material, and made a deliberate decision to withhold it." *Id.* But even showing that an applicant knowingly omitted or misrepresented information is, by itself, insufficient; Relator must further demonstrate that the purported malfeasance was the "but-for" cause of the USPTO issuing the patent, *id.* at 1291, which requires the accuser to provide independent proof of but-for materiality, *see id.* at 1292–93. And because inequitable conduct sounds in fraud, such claims must be pleaded with particularity, again reporting the "who, what, when, where, and how" of the claimed fraudulent conduct. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009); *see also Breville Pty. Ltd. v. Storebound LLC*, No. 12-cv-01783-JST, 2013 WL 1758742, at *3 (N.D. Cal. Apr. 24, 2013). Allegations of specific intent must be "reasonable and drawn from a pleading's allegations of underlying fact." *Exergen Corp.*, 575 F.3d at 1329 n.5. Relator falls far short of these requirements.

To begin with, Relator fails to allege even the basic "who" of any claimed misconduct. Relator names five corporate defendants and attributes the various misrepresentations and omissions to them generally. AC ¶¶ 20–26, 59–82. The duty of candor, however, does not apply to corporations, but specifically to *individuals* appearing before the USPTO.[27] *See* 37 C.F.R. § 1.56; *Avid Identification Sys., Inc.*, 603 F.3d at 974 n.1; *Exergen Corp.*, 575 F.3d at 1329 (citing Manual of Patent Examining Procedures § 2001.01). Accordingly, Courts routinely reject allegations that fail to identify individual wrongdoers. *See, e.g.*, *Exergen Corp.*, 575 F.3d at 1329; *Blackberry Ltd. v. Typo Prods. LLC*, No. 14-cv-00023-WHO, 2014 WL 1867009, at *1–2 (N.D. Cal. May 8, 2014). This Court should also reject Relator's generic allegations.

Relator similarly fails to plead the remaining required elements for inequitable conduct, such as the individual's knowledge of materiality of the misrepresentation and specific intent to deceive the USPTO. *See Breville Pty. Ltd.*, 2013 WL 1758742, at *6. Thus, Relator has not established the necessary foundation for his overarching theory of liability, rendering his entire claim faulty.

But even if Relator were not required to plead a specific "who," the alleged fraudulent conduct

[27] Individuals owing a duty of candor include: the inventor; the preparer or prosecutor of the application; and persons who are substantively involved in the preparation or prosecution of the application and are associated with the inventor or applicant, or anyone who is assigned the application. 37 C.F.R. § 1.56(c)(1)–(3).

suffers from numerous other defects. For instance, certain allegations are not actionable as affirmative statements. *See, e.g.*, AC ¶ 77(a)–(d) (withholding of FDA approval date that had not yet occurred); *id.* ¶ 80(a) (opinion statement that Zytiga was the most successful oral oncology launch of all time); *id.* ¶ 80(b), (f) (speculating as to causes of success). For others, Relator does not even attempt to show "why" the information is material or "'how' an examiner would have used" the information in deciding to allow the patent. *See Exergen*, 575 F.3d at 1329–30; *see, e.g.*, AC ¶ 77(e) (claiming improper market-share metric without evaluating effect on examiner).[28] Still others are predicated on the individual owing the duty being "skilled in the relevant arts" without any facts to suggest that the individual was, in fact, so skilled. *E.g.*, AC ¶ 77(f).

Finally, certain of Relator's allegations are flatly disproven by the very documents he cites. *See Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001) ("The Court need not … accept as true allegations that contradict matters properly subject to judicial notice… ."), *amended on other grounds*, 275 F.3d 1187. As discussed above, *supra* at 9, many of the purported omissions or misrepresentations were clearly disclosed to the patent examiner during patent prosecution. For example, the '213 Patent is specifically disclosed in the specification of the '438 Patent, and the '340 Application examiner expressly acknowledged considering the '213 Patent in Cougar's earlier-filed, subsequently abandoned patent application, *compare* AC ¶ 80(e) *with* RJN, Ex. I at 7, 10; RJN, Ex. J at PDF pg. 22 of 75 (excerpt from '340 patent application), undermining any claim of intent to deceive, *see MONKEYmedia*, 242 F. Supp. 3d at 556–57, or materiality, *see Therasense*, 649 F.3d at 1291. Because Relator has not properly pled fraud on the USPTO years ago, his allegations cannot support an FCA claim today.

D. Relator Has Not Pled Materiality.

Even if Relator could adequately allege the submission of a false claim, he has not pled that the alleged omissions were material to the government's decision to pay the claim. *See Escobar*, 136 S. Ct. at 2003–04. That standard is "demanding" and requires Relator to plead "facts to support allegations of materiality" "with plausibility and particularity." *Id.*

[28] Other allegations are immaterial on their face, such as allegations concerning the short-term efficacy of *all* mCRPC drugs; market advantages from being first to launch; cost; modes of administration; and the overall poor prognosis of mCRPC patients. *See generally* AC ¶ 80.

Here, Relator's allegations are neither plausible nor particular. Rather, the complaint merely recites the materiality standard established by *Escobar*, falling short of *Iqbal*'s pleading standard, *Iqbal*, 556 U.S. at 678, let alone the more rigorous requirements of Rule 9(b). For instance, Relator simply declares that any representation that Zytiga's prices were "fair and reasonable" was necessarily "*per se* material to the government's payment decisions" without adducing *any* facts to explain why. AC ¶ 110. Relator likewise claims without support that "fair and reasonable" pricing (as he incorrectly construes that requirement) is a condition of payment. *Id.* ¶ 111. And Relator then asserts—solely on information and belief—that the government "would not have entered into" contracts to pay for Zytiga had it "known the true facts at the time of contracting or payment." *Id.* ¶ 112. However, "formulaic recitations," devoid of any factual support, are insufficient. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). To the contrary, "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." *Escobar*, 136 S. Ct. at 2001. But Relator does not offer the necessary "something more." *See also Knudsen v. Sprint Commc'ns Co.*, No. C13-04476 CRB, 2016 WL 4548924, at *13 (N.D. Cal. Sept. 1, 2016) (a complaint that "only point[s] to the regulations" to plead materiality "is not sufficient to meet [*Escobar*'s] rigorous standard for pleading materiality").

Moreover, under *Escobar*, Relator must demonstrate that Defendants *knew* the "fair and reasonable" requirement was material to the government's payment of any claim. Relator has made no such allegations. Nor has Relator alleged any facts that would suggest that GSA's "fair and reasonable" pricing requirement would influence other agencies' decisions to pay. For instance, Relator fails to plead that any government has stopped paying for Zytiga in light of Relator's allegations, which were known to them no later than December 2017. The government further obtained actual knowledge of Defendants' alleged violations when it investigated Relator's complaint and elected to *not* intervene. In truth, Relator can make no such claim, as Zytiga remains on the FSS to this day,[29] suggesting that the government has identified no reason to cancel or terminate the contract.[30] In fact, Relator alleges precisely the opposite—that, as of October 2018—the government

[29] *See* RJN, Ex. GG (FSS for Zytiga 250MG Tab); RJN, Ex. HH (FSS for Zytiga 500MG Tab).
[30] The Solicitation grants the GSA the power to review a vendor's books and records to verify that the

"*continues* to pay" claims for Zytiga and that the United States "*continues* to be damaged." AC ¶¶ 121, 122 (emphases added). Relator's allegations that the government continues to pay claims for Zytiga at the negotiated rate strongly indicate that Relator's allegations are not material to the government's decision to pay the price commanded by Zytiga in light of that patent. *Cf. D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) ("The fact that CMS has not denied reimbursement for [defendant's product] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges.").

Finally, because Relator's case necessarily relies on alleged misconduct before the USPTO, his failure to connect the government's decision to pay to that alleged misconduct is particularly problematic. *Cf. Promega*, No. 03-1447-A (E.D. Va. Sept. 24, 2004). For instance, Relator must plead "the effect on the likely or actual behavior of the [government] of the alleged misrepresentation," but Relator does not allege, for example, that the government stops paying claims or reimbursing parties "in the mine run of" cases where a pharmaceutical patent is under challenge. *Escobar*, 136 S. Ct. at 2002–03. Nor would such an allegation merit any weight in light of the statutory mechanisms for generic companies to challenge the validity of pharmaceutical patents when those generics seek to enter the market. Indeed, the IPR process provides a specified, expedited avenue precisely to challenge the validity of patents. Moreover, the Hatch-Waxman Act confers on brand manufacturers the right to institute infringement proceedings upon an ANDA applicant's Paragraph IV certification, which comes with a 30-month exclusivity period, *notwithstanding* potential ongoing claims of invalidity or unenforceability. *See generally* 21 U.S.C. § 355(c)(3)(C). Together, these processes, and the statutorily mandated exclusivity period in particular, firmly suggest that the existence of a claim against a patent would not be material to the government's decision to purchase and pay for that product. Accordingly, Relator would be hard pressed to allege that Defendants' prosecution of the '438 patent—several steps removed from any claim for reimbursement—has any bearing on the government's payment decisions in the "mine run" of cases. *Escobar*, 136 S. Ct. at 2003.

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pricing offered for a good is fair and reasonable. RJN, Ex. H at 22, 53. The GSA "may" also terminate a contract for violation of a term or condition. *Id.* at 6. But "the possibility that the government would be entitled to refuse payment if it were aware of [a defendant's] alleged violations is insufficient by itself to support a finding of materiality." *Kelly*, 846 F.3d at 334.

Collectively, these facts make Relator's case vastly different than those where a relator has "allege[d] more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations." *Campie*, 862 F.3d at 907.

E. Relator Has Not Alleged That J&J Had The Intent to Submit False Claims.

Lastly, Relator also fails to plead the requisite scienter for a false claim: that J&J either "knew that its statements were false, or that it was deliberately indifferent to or acted with reckless disregard of the truth of the statements." *U.S. ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 996 (9th Cir. 2011) (citation omitted). "What constitutes the FCA offense is the knowing presentation of a claim that is either fraudulent or false." *Hopper*, 91 F.3d at 1266 (citation omitted). But any references to scienter in the complaint are nothing more than "formulaic recitation[s]," *Iqbal*, 556 U.S. at 678 (quotation omitted), or conclusory statements—neither of which satisfy Rule 8(b). *E.g.*, AC ¶ 102 (alleging that J&J "knowingly submitted or caused to be submitted False Claims … to secure payments for illegally-inflated prices of abiraterone acetate"); *id.* ¶ 98 (alleging that J&J "knew [it] would be submitting claims … and causing or inducing others to submit claims based on [its] illegally-inflated pricing for Zytiga"). Nor can Relator substitute allegations concerning activity before the USPTO or the FDA in place of scienter as to the false claim. The question is whether J&J knowingly made a false statement at the time the statement was made. *Lee*, 655 F.3d at 996. Therefore, "'some request for payment containing falsities made with scienter (*i.e.*, with knowledge of the falsity and with intent to deceive) must exist.'" *Hopper*, 91 F.3d at 1265. Relator has not sufficiently alleged any such request was made.[31]

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion to dismiss Relator's Amended Complaint, without leave to amend.

[31] For all of the same reasons, Relator has failed to plead a cause of action under the Plaintiff States' statutes, and Relator has further failed to plead any facts in support of Count XXI under the New Mexico Fraud Against Taxpayers Act, AC ¶¶ 350–53.

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